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5 **UNITED STATES DISTRICT COURT**
6 **FOR THE NORTHERN DISTRICT OF CALIFORNIA**
7 **SAN FRANCISCO DIVISION**

8 IN RE: BABY FOOD PRODUCTS
9 LIABILITY LITIGATION

Case No. 24-MD-3101-JSC

MDL 3101

10 M.B., a minor child by and through his
11 Proposed Guardian Ad Litem, Heather
12 Brozana,

Hon. Jacqueline Scott Corley

13 *Plaintiff,*

COMPLAINT AND JURY DEMAND

14 vs.

Case No.

15 GERBER PRODUCTS COMPANY; and
16 WALMART, INC.

17 *Defendants.*
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21 Plaintiff by and through their counsel of record, and for their Complaint against
22 Defendants, hereby alleges as follows:
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INTRODUCTION

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4 1. Defendants *knowingly* sold baby food products contaminated with lead, arsenic,
5 mercury, and cadmium (collectively “Toxic Heavy Metals”). They did this knowing that Toxic
6 Heavy Metals, when consumed by babies, are known to cause brain damage and
7 neurodevelopmental harm. Thus, to the extent Defendants sold baby food that contained detectable
8 amounts of Toxic Heavy Metals (collectively “Contaminated Baby Food”) those products were
9 defective in their manufacture, design, and labeling. Babies are the most vulnerable segment of the
10 population, and they rely on that food for healthy neurodevelopment. Defendants justify this callous
11 disregard for the welfare of babies because, until recently, there were no regulations governing the
12 presence of Toxic Heavy Metals in baby foods – and, because there were no regulations, they were
13 free to do as they pleased.

14
15 2. This lawsuit aims to stop Defendants from poisoning infants with Contaminated
16 Baby Food. Baby Food *should* be safe. It should *not* be contaminated with Toxic Heavy Metals.
17 Period. By sourcing ingredients from farms that have non-detectable level of heavy metal (using
18 sufficiently sensitive testing), avoiding certain ingredients all together, and systematically testing
19 and screening finished products for Toxic Heavy Metals *before* the foods are released for
20 consumption, these Defendants would be able to provide baby food products of detectable levels of
21 Toxic Heavy Metals. And, if some levels are truly unavoidable, or if Defendants believe the
22 identified levels are safe, then, at the very least, Defendants must warn parents/guardians/caregivers
23 about the presence of these Toxic Heavy Metals so they can make informed decisions about what
24 they are feeding their baby. Anything short of proper design, manufacture, and warning, is
25 unacceptable – especially for an industry that touts itself as providing the most important sources of
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1 neurodevelopment for the most vulnerable population of society.

2 3. Plaintiff, here is a child that lives with brain injuries and neurodevelopmental harm
3 caused by exposure to the Defendants' Contaminated Baby Food, which has manifested in a
4 diagnosis of ASD. His parents were never warned that the Defendants' food contained Toxic Heavy
5 Metals and, thus, were never able to make an informed decision about whether to feed their child
6 Defendants' Contaminated Baby Foods. The consequences are stark- there is an unprecedented
7 epidemic of ASD and ADHD spreading throughout the American population, driven, in part, by the
8 systematic neurodevelopmental poisoning of infants from these Defendants' Contaminated Baby
9 Foods.
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12 **PLAINTIFF'S EXPERIENCES AND INJURIES**

13 4. On or about September 2019, Plaintiff M.B. was first exposed to the Contaminated
14 Baby Food.

15 5. Plaintiff M.B. consumed Contaminated Baby Food Products from approximately
16 September 2019 to April 2020.

17 6. Plaintiff M.B. consumed the Contaminated Baby Food Products while residing in
18 Orange County, Florida.
19

20 7. The Contaminated Baby Food was purchased and consumed at least five times per
21 day by Plaintiff M.B., a minor child, with the purpose of nutrition, the use for which Defendants
22 marketed and sold the products.
23

24 8. At all times, the Contaminated Baby Food was consumed by Plaintiff M.B. for the
25 purposes that Defendants market the Baby Food Products.

26 9. After, and as a result of the consumption of Contaminated Baby Foods, Plaintiff
27 M.B. was diagnosed with ASD on or about March 2021.
28

1 state of Florida.

2 15. Defendant WALMART, INC. (“Walmart”) is a citizen of Delaware and Arkansas
3 with its principal place of business located at 702 S.W. 8th St. Bentonville, AK 72716. Walmart
4 sells Baby Foods under the private label brand “Parent’s Choice.” The foods are manufactured by
5 co-manufacturers, but are sold under Walmart’s private label using Walmart’s name. Walmart’s
6 Parent’s Choice offers a wide selection of baby foods ranging from “sweet potatoes & corn” to
7 “toddler cookies” and “yogurt bites.” At all relevant times, Walmart has conducted business and
8 derived substantial revenue from its manufacturing, advertising, distributing, selling, and marketing
9 of Baby Foods within the state of Florida.
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12 **JURISDICTION AND VENUE**

13 16. As an MDL transferee court, this Court has subject matter and personal jurisdiction
14 to the same extent as the respective transferee courts do. In general federal courts have subject
15 matter jurisdiction over each of the actions under 28 U.S.C. § 1332(d) because Plaintiffs are citizens
16 of states other than states where Defendants are citizens. In addition, each Plaintiff seeks damages in
17 excess of \$75,000, exclusive of interest and costs.
18

19 17. This Court has personal jurisdiction over Defendants because their significant
20 contacts related to this litigation in each State makes personal jurisdiction proper over any of them.
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22 18. In particular, this Court has personal jurisdiction over Defendants for cases filed in
23 this District insofar as Defendants are authorized and licensed to conduct business in the State of
24 California, maintain and carry on systematic and continuous contacts in this judicial district,
25 regularly transact business within this judicial district, and regularly avail themselves of the benefits
26 of this judicial district.
27

28 19. Additionally, Defendants caused tortious injury by acts and omissions in this judicial

1 district and caused tortious injury in this district by acts and omissions outside this district while
2 regularly doing and soliciting business, engaging in a persistent course of conduct, and deriving
3 substantial revenue from goods used or consumed and services rendered in this judicial district.

4
5 20. Venue is proper in this District for pretrial purposed for all cases because this
6 litigation was centralized here under 28 U.S.C. § 1407.

7 21. Venue is proper in this District under 28 U.S.C. § 1391(a) for cased filed here
8 because a substantial part of the events and omissions giving rise to those Plaintiff' claims occurred
9 in this district.

10
11 22. Plaintiff files this Complaint pursuant to PTO No. 5, and are to be bound by the
12 rights, protections, and privileges, and obligations of that PTO and other Order of the Court. Further,
13 in accordance with PTO No. 5, Plaintiff hereby designates the United States District Court for the
14 Middle District of Florida as Plaintiff's designated venue ("Original Venue"). Plaintiff makes this
15 selection based upon one (or more) of the following factors.

16
17 ☒ Plaintiff currently resides in Apopka, Florida;

18 ☒ Plaintiff purchased and consumed Defendant(s) products in Orange County, Florida.

19 ☐ The Original Venue is a judicial district in which Defendant _____ resides, and all
20 Defendants are residents of the State in which the district is located (28 U.S.C. 1391(b)(1)).

21 ☒ The Original Venue is a judicial district in which a substantial part of the events or
22 omissions giving rise to the claim occurred, specially (28 U.S.C. 1391(b)(2)): Plaintiff
23 purchased and used the subject Contaminated Baby Food Products, as well as the general
24 location of the Plaintiff's diagnosis and treatment.

25
26 ☐ There is no district in which an action may otherwise be brought under 28 U.S.C. 1391,
27 and the Original Venue is a judicial district in which Defendant _____ is subject to the
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1 Court's personal jurisdiction with respect to this action (28 U.S.C. 1391 (b)(3)),

2 ☐ Other reason (please explain): _____.

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5 **FACTUAL ALLEGATIONS**

6 **I. Rising Concerns Regarding the Presence of Toxic Heavy Metals in Baby Foods**

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8 23. In October 2019, an alliance of nonprofit organizations, scientists and donors name
9 "Happy Babies Bright Futures" ("HBBF"), dedicated to designing and implementing "outcomes-
10 based programs to measurably reduce babies' exposures to toxic chemicals, "published a report
11 investigating the presence of Toxic Heavy Metals in baby foods. The HBBF Report tested 168
12 different baby foods sold on the U.S. market and concluded that "[n]inety-five percent of baby foods
13 tested were contaminated with one or more of four toxic heavy metals- arsenic, lead, cadmium, and
14 mercury. All but nine of the 168 baby foods contained at least one metal; most contained more than
15 one." Specifically, the HBBF report identified "puffs and other snacks made with rice flour,"
16 "[t]eething biscuits and rice rusks," "infant rice cereal," "apple, pear, grape, and other fruit juices,"
17 and "carrots and sweet potatoes" manufactured by the Defendants as particularly high in Toxic
18 Heavy Metals.
19

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21 24. The results of the HBBF report were consistent with that of the U.S. Food and Drug
22 Administration ("FDA") which had, in 2017, detected one or more of the four Toxic Heavy Metals
23 in 33 of 39 types of baby food tested. However, the HBBF reported that "[f]or 88 percent of baby
24 foods tested by HBBF- 148 of 168 baby foods- FDA has failed to set enforceable limits or issue
25 guidance on maximum safe amounts." The HBBF's findings were by no means an outlier. Eights
26 months prior to publication of the HBBF report, a study conducted by scientists at the University of
27 Miami and the Clean Label Project "examined lead...concentrations in a large convenience sample
28

1 of US baby foods.” The study detected lead in 37% of samples.

2 25. Moreover, earlier in 2017, HBBF commissioned a study to evaluate the presence of
3 arsenic in infant rice cereal products sold in the U.S., and the potential risks to children’s
4 neurodevelopment posed by contamination levels. The findings were concerning. The authors
5 concluded that “exposures to arsenic from infant rice cereal approach or exceed existing health-
6 based limits for arsenic levels...leaving little room for additional exposures from other dietary
7 sources, such as snacks, apple juice, and drinking water... Our analyses of arsenic exposures from
8 infant rice cereal during the first year of life suggest that these exposures are not insignificant, and
9 may place infants at risk for adverse health effects.”
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12 **II. Congressional Investigation Finds Substantial Presence of Heavy Metals in Baby Foods**
13 **Manufactured and/or Sold by Defendants, Sparking National Outrage**

14 26. On February 4, 2021, and September 29, 2021, respectively, the U.S. House of
15 Representatives’ Subcommittee on Economic and Consumer Policy, Committee on Oversight and
16 Reform, published two reports detailing its findings that Toxic Heavy Metals—including lead,
17 arsenic, mercury, and cadmium—were present in “significant levels” in numerous commercial Baby
18 Food Products. Four companies—Hain, Gerber (Nestlé), Nurture (Danone), and Beech-Nut—
19 produced internal testing policies, test results for ingredients and finished products, and
20 documentation about what the companies did with ingredients and/or finished products that
21 exceeded their internal testing limits. Three companies—Plum (Campbell), Walmart, and Sprout—
22 initially refused to cooperate.
23

24 27. Congress reported that the data submitted by the companies unequivocally revealed
25 that a substantial number of Defendants’ finished products and/or ingredients used to manufacture
26 the Baby Foods are tainted with Toxic Heavy Metals, namely lead, arsenic, mercury, and cadmium.
27 And, where the Defendants did set internal limits for the amount of metals they allowed in their
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1 foods, Defendants routinely flouted their own limits and sold foods that consistently tested above
2 their limits. Congress found the following:

3 28. **Gerber.** Gerber along with Nestlé used high-arsenic ingredients, using 67 batches of
4 rice flour that had tested over 90 ppb inorganic arsenic. Nestlé and Gerber used ingredients that
5 tested as high as 48 ppb lead; and used many ingredients containing over 20 ppb lead. Nestlé and
6 Gerber rarely test for mercury in their baby foods. In the September 2021 follow-up Congressional
7 report, it was revealed that Nestlé and Gerber’s rice cereal tested up to 116 ppb inorganic arsenic,
8 and their average rice cereal product contained 87.43 ppb inorganic arsenic, which is even higher
9 than the amount contained in Beech-Nut’s average rice cereal product. While Beech-Nut recalled
10 some of its products and completely discontinued sales of its rice cereal, Nestlé and Gerber have
11 taken no such actions to protect children.

12 29. **Walmart.** Walmart refused to cooperate with the House Subcommittee’s
13 investigation into its baby food products, and as such, the Subcommittee was “greatly concerned”
14 that Walmart “might be obscuring the presence of higher levels of toxic metals in their baby food
15 products.” The Subcommittee noted that independent data from HBBF Report confirmed that
16 Walmart’s baby foods are indeed tainted. For example, the HBBF Report observed that one of
17 Walmart’s products contained 56.1 ppb total arsenic, and 26.1 ppb cadmium. Another product
18 contained 108 ppb total arsenic, 66 ppb inorganic arsenic, 26.9 ppb lead, and 2.05 ppb mercury.

19 30. Following the publication of the Subcommittee Report, Walmart provided documents
20 to the Subcommittee. On September 29, 2021, the House Subcommittee released a subsequent report
21 entitled “New Disclosures Show Dangerous Levels of Toxic Heavy Metals in Even More Baby
22 Foods.” The Subcommittee report addendum described the documents from Walmart as “revealing a
23 concerning lack of attention to toxic heavy metal levels in baby food and an abandonment of its
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1 previously more protective standards.” Walmart does not appear to conduct any testing of its baby
2 food products. Walmart sets maximum arsenic and lead levels and asks the manufacturer of its
3 private label to self-certify, but Walmart does not appear to collect any test data or check the
4 accuracy of those certifications. Walmart does not require any mercury or cadmium testing and does
5 not set any standards for mercury or cadmium levels.
6

7 31. The metal concentrations discussed above and further below surpass the limits
8 allowed by U.S. regulatory agencies. There are no FDA final regulations governing the presence of
9 Toxic Heavy Metals in the majority of Baby Foods with the exception of 100 ppb inorganic arsenic
10 in infant rice cereal and proposed (not yet final) limits for lead in certain baby food categories. To
11 the extent such regulations exist, the quantities of Toxic Heavy Metals in Defendants’ Baby Foods
12 exceed any permissible FDA levels. To be sure, the FDA has set the maximum contaminant levels
13 (“MCL”) in bottled water at 10 ppb inorganic arsenic, 5 ppb lead, and the EPA has capped the
14 allowable level of mercury in drinking water at 2 ppb. However, these limits were created in
15 reference to *adult* exposure, not infants. Compared to these thresholds, the test results of the
16 Defendants’ baby foods and their ingredients are multiple folds greater than the permitted metal
17 levels. Moreover, compounding these troubling findings, the Defendants set internal limits for the
18 presence of Toxic Heavy Metals in their foods that were, themselves, dangerously high and then
19 routinely failed to abide by those inadequate standards, as discussed below.
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23 32. As Congress observed, the Defendants have willfully sold—and continue to sell—
24 contaminated Baby Foods notwithstanding their full awareness of these unacceptably high levels of
25 Toxic Heavy Metals in their products.
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27 **III. Defendants Engaged in a Pattern and Practice of Selling Contaminated Baby Foods and Failed to Reduce Metal Levels**

28 33. Several factors drive the Toxic Heavy Metal contamination of Defendants’ baby

1 foods, all of which are within Defendants' control.

2 34. *First*, at various times, all Defendants sourced ingredients that contained elevated
3 levels of Toxic Heavy Metals. These ingredients were then used to manufacture the baby foods
4 consumed by Plaintiff, thereby exposing Plaintiff to Toxic Heavy Metals that cause brain damage
5 and other neurodevelopmental harm. One way for Defendants to "deal" with this issue involved
6 relegating any testing of Toxic Heavy Metals to suppliers and co-manufacturers, who were required
7 to certify that Toxic Heavy Metals were below a certain threshold. Defendants would audit those
8 results, discover that the reported certifications were false or inaccurate, and then take no action to
9 stop the use of those ingredients or finished products.
10

11 35. *Second*, some Defendants implemented dangerously high internal limits
12 ("specifications" or "specs") for the maximum level of Toxic Heavy Metals that Defendants allowed
13 in the baby foods. Such high limits—untethered to any consideration of the low levels at which
14 metals are capable of damaging babies' brains—allowed Defendants to source and use ingredients
15 that contained elevated Toxic Heavy Metals to manufacture the baby foods consumed by Plaintiff. In
16 the highly competitive and lucrative baby food market, using contaminated ingredients allows each
17 Defendant to retain greater market share.
18

19 36. *Third*, some Defendants failed to implement any internal specifications for the
20 amount of Toxic Heavy Metals allowed in ingredients or finished baby foods. By simply not looking
21 at the issue, certain highly contaminated ingredients and finished products were allowed to be used
22 and sold to consumers. This would happen notwithstanding the Defendants' specific knowledge of
23 the risk of Toxic Heavy Metals and their presence in ingredients and finished products.
24

25 37. *Fourth*, Defendants did not routinely adhere to their own internal metal specifications
26 or standards, allowing contaminated ingredients and finished products to be released as "exceptional"
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1 releases” or other simpler terminology. This resulted in ingredients being used and baby foods
2 manufactured and sold that contained levels of Toxic Heavy Metals far higher than what was
3 internally set by Defendants. In other instances, Defendants would test products that had been put
4 on the market after-the-fact, learn about the products containing extremely high levels of Toxic
5 Heavy Metals, and then take no action to recall the product or warn consumers about the issue.
6

7 38. *Fifth*, upon information and belief, Defendants’ manufacturing practices also
8 contributed to contamination. For example, the water used at some of the facilities where the baby
9 foods were manufactured contained Toxic Heavy Metals which, in turn, ended up in the finished
10 baby food product sold for consumption by babies.
11

12 39. **Gerber.** Gerber tested ingredients and, occasionally, finished products. However,
13 while Gerber was the only Defendant to test both ingredients and finished products with any
14 regularity, they set high heavy metal limits that rendered their food unsafe. For baby foods
15 generally, between 2012 and 2019, Gerber set a limit of 40 ppb for lead, 20 ppb for arsenic, and 10
16 ppb for mercury. For infant rice cereal, between 2012 and 2017, Gerber set a lead limit of 100 ppb,
17 with a “target” of 50 ppb in 2016 and 2017. Between 2018 and 2019, Gerber set a lead limit for 50
18 ppb. For arsenic in rice cereal, between 2012 and 2015, Gerber did not have a limit, merely a target
19 of 100 ppb. Then, between 2016 and 2018, it set the arsenic limit at 100 ppb. By 2019, Gerber
20 increased the arsenic limit to 130 ppb for cereals with 90% rice (and kept the limit at 100 ppb for
21 other cereals). For snack foods, Gerber had a lead limit of 150 ppb between 2012 and 2014. It was
22 reduced to 100 ppb in 2016 and 2017, and then went down to 50 ppb in 2018 and 2019. There was
23 no limit for arsenic in snack food prior 2016, just a “target” of 100 ppb. Then a 100-ppb arsenic
24 limit was set starting in 2016. For both infant cereal and snacks, Gerber imposed a 30-ppb limit for
25 mercury in infant cereal between 2012 and 2016, and reduced it to 10 ppb from 2017 onward. With
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1 these exceptionally high limits, Gerber sold baby foods that were dangerous for infant consumption.
2 They did this knowingly.

3 40. Gerber would also audit and re-test Toxic Heavy Metal results submitted by
4 suppliers, and find that the certification from suppliers were incorrect or false. Gerber would
5 nonetheless use the certified results and release products despite the ingredients not meeting
6 specifications or being safe for infant consumption.

7
8 41. Gerber often used high-arsenic ingredients, for example, using 67 batches of rice
9 flour that had tested over 90 ppb inorganic arsenic. Furthermore, Gerber regularly sold baby food
10 products testing over 100 ppb arsenic, at times reaching 116 ppb, and their average rice cereal
11 product contained 87.43 ppb inorganic arsenic. Indeed, this is why Congress noted that “Gerber’s
12 organic rice cereal is dangerous...” In other instances, Gerber permitted as much as 300 ppb of
13 arsenic in the rice flour ingredient used to manufacture its U.S. baby foods, notwithstanding the fact
14 that Gerber often implemented stricter standards for baby foods sold in other countries.

15
16 42. Gerber’s baby foods are also contaminated with elevated levels of lead. Gerber used
17 ingredients that tested as high as 48 ppb lead and used many ingredients containing over 20 ppb lead.
18 Furthermore, Gerber sold baby food products testing at and/or above 50 ppb of lead. Indeed, Gerber
19 have historically permitted as much as 150 ppb lead in their baby food products. Although Gerber
20 was fully aware that it was very feasible to source lower-lead ingredients, they proceeded to use
21 high-lead ingredients in their baby foods. Gerber rarely tests for mercury in their baby foods. This
22 is notwithstanding the fact that mercury is known to contaminate ingredients such as rice and poses a
23 severe risk to babies’ brain development.

24
25 43. The February 4, 2021 Congressional Report found Gerber carrots tested for cadmium
26 at levels above 5 ppb, with some containing more than 87 ppb of cadmium. These are exceptionally
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28

1 high levels.

2 44. Moreover, compounding these troubling findings, Gerber historically only tested
3 certain ingredients of its baby food products and only occasionally tested the
4 finished products consumed by babies. It was not until recently that Gerber started to implement
5 finished product testing on a more regular basis.

7 45. Gerber have known since at least the 1990s that inorganic arsenic was neurotoxic and
8 caused developmental issues. Despite this knowledge, in 2012, when Gerber's infant rice cereal was
9 on the front page of a Consumer Report article on arsenic, a Gerber spokesperson told the public that
10 arsenic in baby food posed no health risk.

12 46. **Walmart.** Walmart sold baby food under a "private" brand called "Parent's Choice",
13 which was manufactured by a different supplier but branded, promoted, and sold as a Walmart
14 product. Walmart did not test it for Toxic Heavy Metals whatsoever. Instead, Walmart required
15 certain specifications be met for the products provided by its suppliers, which included some limits
16 of heavy metals. These specifications were not enforced in any way. Walmart did not require the
17 submission of testing from suppliers, nor did it do any of its own testing.

19 47. The only efforts to police Toxic Heavy Metals in their Parent's Choice baby food
20 involved generic specifications for lead and arsenic—there were no other specifications or limits for
21 other Toxic Heavy Metals—which for most baby food products resulted in there being no limits. The
22 following chart reflects Walmart's Toxic Heavy Metal specifications prior to December 2018.

Type of Food	Lead	Arsenic	Mercury	Cadmium	Aluminum
Dry baby food with no juice or nectar	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>
Dry baby food with juice or nectar	50 ppb	23 ppb	<i>None</i>	<i>None</i>	<i>None</i>
Wet baby food with no juice or nectar	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>

Wet baby food with juice or nectar	50 ppb	23 ppb	<i>None</i>	<i>None</i>	<i>None</i>
Yogurt baby food products	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>

48. In December 2018, Walmart changed its specification to 100 ppb of inorganic arsenic for all dry baby foods, making the products even less safe. Thus, for the vast majority of Walmart's baby food products, there was never a limit for any Toxic Heavy Metals.

IV. Defendants Abandon Efforts to Reduce Metal Levels in Baby Foods

49. In 2019, as concerns grew over contamination of certain baby foods on the U.S. market, a consortium of the Defendants comprised of Beech-Nut, Plum/Campbell, Gerber, Hain, Nurture, and Sprout, as well as certain interested third party groups such as the Environmental Defense Fund ("EDF") and HBBF, were formed with the intention "of reducing heavy metals in young children's food."

50. The consortium was named the Baby Food Council ("BFC"). The BFC involved the sharing of common testing data on the levels of metal contamination of Defendants' baby foods, a grant to Cornell University to further study the issue, and a proposed "voluntary Baby Food Standard to limit the amounts of heavy metals in baby food." The BFC specifically recognized the risk of neurodevelopmental harm caused by Toxic Heavy Metals to the developing brain of infants and that there were no safe levels of exposure.

51. The Baby Food Standard "would have provided companies with a common framework for progressively reducing contaminants by regularly testing products and improving management practices, and for being transparent with consumers about the safety of their products."

52. After several years of negotiations and discussions, including a proposed system for testing, the EDF and HBBF proposed voluntary limits of 1 ppb for lead. The baby food companies, however, rejected the proposal outright. Participation in the BFC was little more than a façade—

1 they had no intention of self-regulating their products as it related to Toxic Heavy Metals.

2 53. This led EDF and HBBF to leave the BFC in protest in 2021. They explained their
3 departure publicly, noting that Defendants “all decided to backpedal on this project—even though
4 the standard was designed to protect babies’ brain development” and provide adequate notice to
5 consumers regarding the presence of Toxic Heavy Metals on Baby Food labeling. EDF explained:
6

7 EDF cofounded the Council because we believed there was a shared commitment to
8 reduce levels of lead, arsenic and cadmium in baby food products to better protect
9 children’s developing brains from these toxins... Unfortunately, the companies chose
10 to cease the Council’s development of a voluntary Baby Food Standard that it had
11 begun in late 2020. The Standard would have provided companies with a common
12 framework for progressively reducing contaminants by regularly testing products and
13 improving management practices, and for being transparent with consumers about the
14 safety of their products. Negotiations failed to provide an alternative approach that
15 EDF felt was sufficient to drive down levels of lead, arsenic and cadmium in baby
16 food.”

17 54. HBBF explained:

18 Healthy Babies Bright Futures is focused on tangibly reducing neurotoxic exposures
19 to babies. The baby food companies’ refusal to jointly set limits for heavy metals in
20 baby food has shown that the Council will no longer be the powerful mechanism for
21 this important work that the initial plans had promised. The baby food companies’
22 decision to stop progress on a voluntary standard for heavy metals in baby food is a
23 disappointment...What started as dedication has turned into delay and intention has
24 become inaction. So HBBF has decided to put our effort into other initiatives that
25 will move the needle on this important issue.

26 55. In short, the Defendants opted to continue “self-regulating,” the same self-regulation
27 which exposed—and continued to expose—Plaintiff to Toxic Heavy Metals in Defendants’ baby
28 foods.

29 **V. The Dangers of Toxic Heavy Metals and Metal Exposure Through Consumption of 30 Baby Foods**

31 56. According to the World Health Organization (“WHO”), Toxic Heavy Metals,

1 specifically lead, arsenic, mercury, and cadmium pose a “major public health concern” for children.
2 The Occupational Safety and Health Administration (“OSHA”) has warned that these metals “may
3 build up in biological systems and become a significant health hazard.” Indeed, the Department of
4 Health and Human Services’ Agency for Toxic Substances and Disease Registry (“ATSDR”) ranks
5 arsenic as number *one* among substances present in the environment that pose the most significant
6 potential threat to human health, followed by lead (second), mercury (third), and cadmium (seventh).
7

8 57. The threat presented by Toxic Heavy Metals to children’s health is widely shared by
9 the global regulatory and scientific community. For example, the FDA has set an Interim Reference
10 Level (“IRL”) of 2.2 micrograms/day for lead exposure through baby food products. That is the
11 amount of lead exposure at or above which the agency considers associated with adverse
12 neurodevelopmental effects in babies. The FDA, in its guidance documents for inorganic arsenic
13 and lead in baby food products has repeatedly acknowledged the dangers of heavy metals to the
14 neurodevelopment of infants.
15

16
17 Even low lead exposure can harm children’s health and development,
18 specifically the brain and nervous system. Neurological effects of lead exposure
19 during early childhood include learning disabilities, behavior difficulties, and
20 lowered IQ. Lead exposures also may be associated with immunological,
21 cardiovascular, renal, and reproductive and/or developmental effects...Because
22 lead can accumulate in the body, even low-level chronic exposure can be
23 hazardous over time...Even though no safe level of lead exposure has yet been
24 identified for children's health, the IRL serves as a useful benchmark in
25 evaluating the potential for adverse effects of dietary lead. In particular, FDA is
26 focused on the potential for neurodevelopmental effects from lead exposure, as
27 review of the scientific literature indicates that *such adverse effects*
28 *of lead consistently occur at a blood lead level associated with FDA’s IRL for*
children. (emphasis added).

58. As one recent study observed, “[t]he implications of heavy metals with regards to
children’s health have been noted to be more severe compared to adults. The elements’ harmful

1 consequences on children health include mental retardation, neurocognitive disorders, behavioral
 2 disorders, respiratory problems, cancer and cardiovascular diseases. Much attention should be given
 3 to heavy metals because of their high toxicity potential, widespread use, and prevalence.” Children
 4 and, even more so, babies have higher exposure to metals compared to adults because they consume
 5 more food in relation to their body weight and absorb metals more readily than adults by 40 to 90%.

7 59. The mechanisms needed to metabolize and eliminate heavy metals are comparatively
 8 undeveloped in childhood, with babies having weaker detoxifying mechanisms and poorer immune
 9 systems than adults. For example, liver pathways that in adulthood metabolize absorbed arsenic do
 10 not mature until mid-childhood; un-excreted arsenic thus continues to circulate and is deposited in
 11 other organs. According to Linda McCauley, Dean of the Nell Hodgson Woodruff School of Nursing
 12 at Emory University, who studies environmental health effects, “[n]o level of exposure to these
 13 [heavy] metals has been shown to be safe in vulnerable infants.”

15 60. Thus, “the major windows of developmental vulnerability occur during infancy and
 16 early childhood due to continuing brain development after birth.” In short, even small amounts of
 17 exposure to Toxic Heavy Metals can have devastating health outcomes for babies and children.

19 **A. Exposure to Toxic Heavy Metals Has Been Consistently Associated with**
 20 **Neurodevelopmental Harm, i.e., Autism and ADHD in Pediatric Populations**

21 61. It is well-known that exposure to Toxic Heavy Metals in early life can interfere with
 22 neurodevelopment at exceedingly low levels of exposure. And, one of the ways in which such
 23 interference with neurodevelopment can present in a child is in the form of the neurodevelopmental
 24 disorders ASD and ADHD. As the U.S. Centers for Disease Control observed in its 2020
 25 Toxicological Profile for Lead, at just ≤ 10 $\mu\text{g/dL}$: “The following neurobehavioral effects in children
 26 have been associated with [lead]: “Altered mood and behaviors that may contribute to learning
 27 deficits, including *attention deficits, hyperactivity, autistic behaviors*, conduct disorders, and
 28

1 delinquency.” (emphasis added). Likewise, the NIH states: “prenatal and early childhood exposure
2 to heavy metals...may be linked to autism spectrum disorder.”

3 62. Such conclusions have likewise been reached by a consortium of the country’s
4 leading epidemiologists, pediatricians, and medical groups, noting that Toxic Heavy Metals such as
5 lead and mercury are “prime examples of toxic chemicals that can contribute to learning, behavioral,
6 or intellectual impairment, as well as specific neurodevelopmental disorders such as ADHD or
7 autism spectrum disorder.”
8

9 63. Multiple studies, reviews, and meta-analyses conducted throughout various parts of
10 the world over the last decade have consistently observed that early life exposure to heavy metals
11 can cause brain injury and, specifically, brain injury which manifests as ASD.
12

13 64. For example, four meta-analyses published in 2014, 2017, 2019 and 2020,
14 respectively, observed consistent associations between exposure to arsenic, cadmium, and mercury
15 and ASD in children; with the authors in all three studies recommending – based on the data – that
16 exposure to such metals in children be reduced as much as possible, and one of the study authors
17 specifically concluding that “Results of the current meta-analysis revealed that mercury is an
18 important causal factor in the etiology of ASD.”
19

20 65. In a recent 2017 NIH-funded prospective observational study, the authors examined
21 the risk of ASD outcome in twins based on their respective body burden of lead. The study
22 concluded in no uncertain terms that “prenatal and early childhood disruption (excess or deficiency)
23 of multiple metals during critical developmental windows is associated with ASD, and suggests a
24 role for elemental dysregulation in the etiology of ASD.”
25

26 66. Similarly, a large, prospective study from 2016 in Korean school children observed
27 that low levels of lead exposure in early life are associated with autism, the authors specifically
28

1 concluding: “even low blood lead concentrations...are associated with more autistic behaviors...
2 underscoring the need for continued efforts to reduce lead exposure.”

3 67. Studies have repeatedly observed strong associations between exposure to cadmium
4 and aluminum and neurodevelopmental disorders such as ASD, as observed by a recent study:
5 “Environmental exposure to...cadmium (Cd)... and aluminum (Al) has been associated with
6 neurodevelopmental disorders including autism spectrum disorder (ASD).” For example, a study
7 from 2014 evaluated the body burden of lead, cadmium, and arsenic in children with autism
8 compared to controls and noted that, in addition to lead and arsenic, “our study demonstrated
9 elevation in the levels of...cadmium...in a child with autism,” while an earlier study noted that
10 “autism may be associated with significant alterations of some rare element concentrations,
11 including Cd...” Such results have been confirmed by meta-analyses which “*show significant*
12 *associations* between ASD and the metals Al [and] Cd.” And, such earlier data is further supported
13 by recent research, with a 2023 systematic review and meta-analysis concluding that “compared with
14 the healthy control group, the ASD group had higher concentrations of Cd, Pb, arsenic, and Hg.
15 These 4 heavy metals play different roles in the occurrence and progression of ASD.”

16 68. Repeated associations between early life Toxic Heavy Metal exposure and ASD have
17 also been observed during the pre-natal timeframe, lending further strength to the findings of post-
18 natal studies. For example, in a 2021 study by Skogheim and colleagues, the authors prospectively
19 assessed the relationship between pre-natal metal exposure in various biomarkers and autism risk.
20 The study concluded that “[r]esults from the present study show several associations between levels
21 of metals and elements during gestation and ASD and ADHD in children. The most notable ones
22 involved arsenic...mercury...and lead. Our results suggest that even population levels of these
23 compounds may have negative impacts on neurodevelopment.”

1 69. Similarly, in a study by the research group assessing the New Hampshire Birth
2 Cohort, the authors evaluated the neurotoxic effects of heavy metals during various stages of
3 pregnancy and concluded: “Our results support the hypothesis that exposure to...As in mid to late
4 pregnancy may be neurodevelopmentally harmful.”

5
6 70. Such results have been replicated in studies throughout the world, including China,
7 Korea, the U.S., Europe, and Egypt, implicating arsenic, mercury, and lead in pediatric diagnoses of
8 autism and autistic behaviors, with a 2018 Chinese study concluding: “[t]he results of this study are
9 consistent with numerous previous studies, supporting an important role for heavy metal exposure,
10 particularly mercury, in the etiology of ASD.” Indeed, a 2015 Egyptian study noted
11 “[e]nvironmental exposure to these toxic heavy metals, *at key times in development*, may play a
12 *casual* role in autism.” (emphasis added).

13
14 71. Exposure to Toxic Heavy Metals, specifically lead, has also been repeatedly
15 associated with the development of ADHD in children, as demonstrated by numerous studies.

16
17 72. No fewer than four large meta-analyses, conducted in four different continents (North
18 America, America, South America, Europe and Asia), and some employing a cross-sectional design,
19 have observed a consistent association between various metals and ADHD in children. Indeed, the
20 authors of the meta-analysis from Spain noted that “the evidence from the studies allowed us to
21 establish that there is an association between lead and ADHD and that even *low levels of lead raise*
22 *the risk*.” (emphasis added).

23
24 73. The findings from the meta-analyses have been replicated in several Chinese studies
25 from 2006, 2014, and 2018, respectively. Notably, the authors of the 2014 Chinese study observed
26 that “[e]xposure to lead even at low levels correlates with attention-deficit/hyperactivity disorder
27 (ADHD). However, lead-contaminated environments are often *contaminated with other heavy*
28

1 *metals that could exacerbate lead-induced ADHD.*” (emphasis added). This is particularly
2 relevant—and disturbing—as children who consumed Defendants’ baby foods were repeatedly
3 exposed to a cocktail of Toxic Heavy Metals that, synergistically, further increased their risk of
4 developing ADHD.

5
6 74. Moreover, studies have observed a dose-response relationship between exposure to
7 Toxic Heavy Metals and ADHD, as demonstrated by the 2016 Spanish study Donzelli, *et al.* Another
8 2016 cross-sectional study from Spain was conducted on 261 children aged 6-9 to examine the
9 association between exposure to arsenic and ADHD. After adjusting for potential confounders, the
10 authors observed a dose-response relationship between urine arsenic levels and inattention and
11 impulsivity scores, concluding that “[urine arsenic] levels were associated with impaired
12 attention/cognitive function, *even at levels considered safe.* These results provide additional
13 evidence that postnatal arsenic exposure impairs neurological function in children.” (emphasis
14 added.)

15
16
17 75. The fact that such results, and many more, have been observed in multiple studies,
18 conducted by different researchers, at different times, in different parts of the world, in children of
19 multiple ages, utilizing different study methods (prospective, case-control and cross-sectional
20 epidemiological analyses) and measuring a variety of end-points (including hair, blood, and urine),
21 strongly supports a causal relationship between exposure to Toxic Heavy Metals and the
22 development of ASD and ADHD in children.

23
24 **B. Defendants’ Baby Foods Contain Toxic Heavy Metals Capable of Interfering with**
25 **Early Neurodevelopment**

26 76. As illustrated above, Toxic Heavy Metal exposure is capable of inflicting damage to
27 the developing brain at extremely low doses. And, upon information and belief, Defendants
28 manufactured and sold baby foods containing Toxic Heavy Metals that can, under certain

1 circumstances (based upon the genetic susceptibilities, medical history, and other factors of the
2 exposed child) interfere with a baby's neurodevelopment sufficient to cause conditions such as ASD
3 and ADHD.

4
5 77. As an initial matter, the study commissioned by HBBF and discussed above
6 specifically evaluated the propensity for arsenic exposure through consumption of infant rice cereal
7 to impact early life neurodevelopment. Following analyses of the levels of arsenic exposure from
8 consumption of infant rice cereal, the authors concluded "that high consumers of infant rice cereal
9 (i.e., infants eating three servings per day) eating products currently on the U.S. market would have a
10 daily arsenic intake of 0.35-0.67 $\mu\text{g/kg bw/day}$...per the Tsuji et al. (2015) lower-bound estimate for
11 an RFD for the neurodevelopmental effects of arsenic (0.4 $\mu\text{g/kg bw/day}$), high consumers of infant
12 rice cereal may also be at risk for this endpoint. Even in average consumers of infant rice cereal
13 (i.e., one serving per day), our estimates of arsenic intakes (0.15 to 0.29 $\mu\text{g/kg bw/day}$) leave little
14 room for exposures to arsenic from other sources." Thus, consumption of Defendants' baby foods,
15 including but not limited to infant rice cereal and rice-based snack baby food products manufactured
16 and sold by Defendants can expose babies to levels of arsenic above that associated with
17 neurodevelopmental harm in the scientific literature.

18
19 78. Defendants manufactured and sold baby food products that, with just a couple of
20 servings, are capable of exposing a baby to lead levels at or above the 2.2 $\mu\text{g/day}$ considered by the
21 FDA to be associated with neurodevelopmental harm. Each source of lead exposure is cumulative—
22 making any detectable amount of Toxic Heavy Metal in baby food a contributing factor to potential
23 neurodevelopmental harm.

24
25 79. Similarly, upon information and belief, Defendant Hain was aware of the neurotoxic
26 propensities of lead, arsenic, and mercury at low levels, but proceeded to manufacture and sell Baby
27
28

1 Foods containing arsenic and lead levels that, upon information and belief, Hain considered as
2 capable of inflicting neurodevelopmental harm.

3 **VI. Defendants Knowingly Sold Baby Foods Containing Toxic Heavy Metals and Knew or**
4 **Should Have Known of the Risks of Such Exposures in Children and Thus Breeched**
5 **their Duty of Care in Selling Contaminated Baby Foods**

6 80. During the time that Defendants manufactured and sold baby foods in the United
7 States, the weight of evidence showed that Defendants' baby foods exposed babies and children to
8 Toxic Heavy Metals. Defendants failed to disclose this risk to consumers through any means.

9
10 81. As discussed above, both independent testing, the Defendants' internal evaluations of
11 their baby foods, and the Defendants' representations and disclosures to Congress and the FDA
12 reveal the presence of Toxic Heavy Metals in Defendants' products. As such, Defendants knew or
13 should have known that their baby foods contain Toxic Heavy Metals with an attendant risk of
14 causing neurodevelopmental harm.

15
16 82. Indeed, independent testing performed in early 2019 demonstrated elevated amounts
17 of such Toxic Heavy Metals in Baby Food products on the U.S. market, and the HBBF Report
18 further confirmed such contamination of Defendants' baby foods. And, as the Congressional
19 investigation found, the Defendants continued to sell their baby foods even after testing of both
20 ingredients and finished products revealed the presence of Toxic Heavy Metals.

21
22 83. Moreover, the scientific literature on the dangers of Toxic Heavy Metals—
23 particularly as it relates to adverse effects on the neurodevelopment of children—have been well
24 known for decades. Defendants, as manufacturers and sellers of baby foods, are held to the standard
25 of experts and responsible for keeping abreast of the latest scientific developments related are held to
26 the dangers of contaminants in their products. Defendants failed to take action to protect vulnerable
27 children from exposure to the Toxic Heavy Metals in their foods and, thus, subjected them to the risk
28

1 of brain injury which can manifest as neurodevelopmental disorders such as ASD, ADHD, and
2 related *sequelae*.

3 84. To be clear, the Defendants are able to manufacture baby foods that do not pose such
4 a dangerous risk to the health of infants and children by using alternative ingredients, not adding
5 certain pre-mix minerals and vitamins high in Toxic Heavy Metals or sampling their ingredients
6 from other sources. At the very least, Defendants were under a duty to warn unsuspecting parents of
7 the presence of Toxic Heavy Metals in their Baby Foods.

8
9 **VII. Defendants' Baby Food Products Were Defective Due to Insufficient Warnings,**
10 **Manufacturing Defects, and/or Design Defects to the Extent the Baby Food Products**
11 **Contained Detectable Levels of Toxic Heavy Metal**

12 85. All of Defendants' baby food products that contained detectable levels of Toxic
13 Heavy Metals (or constituted finished products wherein the ingredients contained detectable levels
14 of Toxic Heavy Metals), assuming state of the art analytical testing, were defective as it relates to
15 warnings because no Defendant has ever warned about the presence of Toxic Heavy Metals in their
16 baby foods. Because discovery is ongoing, a complete list of Defendants' specific baby foods that
17 contained detectable levels of Toxic Heavy Metals is not known at this time. Based on publicly
18 available testing data, including data reported by HBBF and Congress, the vast majority of
19 Defendants' products contain detectable levels of Toxic Heavy Metals in them, rendering them each
20 defective as it relates to warnings. Attached as Appendix A to this Complaint is a list of the
21 Defendants' products now known to be defective. This list, however, is not comprehensive and
22 shall be amended as discovery is obtained.

23
24 86. Defendants' baby food products are also defective as manufactured, as they contain
25 detectable Toxic Heavy Metals which are not supposed to be there, by design. Toxic Heavy Metals
26 do not provide any nutritional or therapeutic value to infants or fully-grown humans. They are only
27
28

1 poisonous to neurodevelopment. None of these baby food products, by design, should contain Toxic
2 Heavy Metals in them and, thus, to the extent the products contain detectable levels of Toxic Heavy
3 Metals in them, those are manufacturing defects. Based on publicly available data, most of
4 Defendants' baby food products contain some detectable levels of Toxic Heavy Metals in them.
5 However, as the levels of Defendants' baby food products are not known yet, nor do Plaintiff have a
6 complete list of Defendants' baby food products or their formulations—information that will be
7 obtained through discovery—Plaintiff cannot identify each baby food product that contained a
8 manufacturing defect. However, Appendix A is a running list of baby food products sold by
9 Defendants.
10
11

12 87. If Defendants specifically designed their baby food products to contain Toxic Heavy
13 Metals, meaning their presence was not the product of a manufacturing defect, then the products
14 were defective by design. Toxic Heavy Metals should not be present in foods that are being
15 consumed by infants and products should be designed to not have detectable levels of toxic heavy
16 metal in them. Such designs are easily accomplished, by only using ingredients that contain non-
17 detectable levels of Toxic Heavy Metals and by testing finished products, before release, to ensure
18 they do not contain Toxic Heavy Metals within them. This is possible because there are examples of
19 Defendants' finished products not containing detectable levels of Toxic Heavy Metals—even if, for
20 that same products, there are instances where they did. Thus, Defendants were able to design baby
21 food products to not contain detectable levels of toxic heavy metals, and to the extent that each
22 Defendants' design contemplated there being detectable levels of Toxic Heavy Metals in baby food,
23 the design, itself, was defective. Because Plaintiff does not know the Defendants' intended design
24 for their baby food products—as there has been no discovery obtained to date concerning product
25 formulation, product/ingredient specifications, and testing methodologies/capabilities—Plaintiff
26
27
28

1 cannot specify which baby food products were defectively designed versus which ones were not.
2 That said, Appendix A, a running list of the Defendants' baby food products that, with further
3 discovery, may yield information that will allow Plaintiff to identify whether the product was
4 defectively designed.
5

6 88. Whether the Defendants' products were defective due to inadequate warnings,
7 manufacturing errors, or by design, the existing publicly available evidence indicates that
8 consumption of Defendants' baby food products can expose infants to Toxic Heavy Metals, and that
9 depending on specific milieu of products consumed by each Plaintiff and each Plaintiff's specific
10 susceptibility and circumstances, Defendants' baby food products contributed to each Plaintiff's
11 Toxic Heavy Metal burden during critical period of infant neurodevelopment. Plaintiff, thus, alleges
12 that this cumulative exposure from Defendants' products to Toxic Heavy Metals, substantially
13 contributed to causing neurodevelopmental harm that manifested as ASD and/or ADHD. Moreover,
14 each Plaintiff alleges that had these baby food products not been defective—by having sufficient
15 warnings, being correctly manufactured, and/or designed properly—each Plaintiff would not have
16 been exposed to levels of Toxic Heavy Metals in Defendants' baby food products that would have
17 contributed to the neurodevelopmental harm that manifested as ASD and/or ADHD.
18

19 **VIII. Exemplary/Punitive Damages Allegations**

20 89. Defendants' conduct as alleged herein was done with reckless disregard for human
21 life, oppression, and malice. Defendants' conduct is particularly reprehensible given that their toxic
22 foods were directed at vulnerable babies—a population group far more susceptible than adults to the
23 neurotoxic dangers of heavy metals.
24

25 90. Defendants were fully aware of the safety risks of Contaminated Baby Foods,
26 particularly the dangerous potential of Toxic Heavy Metals on neurodevelopment in infants and
27
28

1 children. Nonetheless, Defendants deliberately crafted their label, marketing, and promotion to
 2 mislead consumers. Indeed, Defendants repeatedly market their baby foods as safe for consumption
 3 and go so far as claiming that they adhere to “the strictest standards in the world;” and provide
 4 “baby’s food full of nutrition while meeting standards strict enough for tiny tummies,” as well as
 5 other statements and representations that hold out their baby foods as safe for consumption by
 6 infants. Indeed, each Defendant falsely reassured parents/guardians/caregivers that their baby foods
 7 would foster healthy neurodevelopment when consumed even though they knew their baby foods
 8 exposed infants’ developing brains to potent neurotoxic heavy metals. In actual fact, as discussed
 9 above, Defendants routinely sold Contaminated Baby Foods, regularly flouted their own internal
 10 limits of Toxic Heavy Metals and failed to disclose to consumers that their products contained such
 11 dangerous contaminants.

14 91. This was not done by accident or through some justifiable negligence. Rather,
 15 Defendants knew they could profit by convincing consumers that their baby foods were healthy and
 16 safe for infants, and that full disclosure of presence and/or risks of the Toxic Heavy Metals present
 17 in the baby foods would limit the amount of money Defendants would make selling the products.
 18 Defendants’ object was accomplished not only through a misleading label, but through a
 19 comprehensive scheme of selective misleading research and testing, failure to test, false advertising,
 20 and deceptive omissions as more fully alleged throughout this Complaint.
 21 Parents/guardians/caregivers were denied the right to make an informed decision about whether to
 22 purchase Defendants’ baby food for their babies without knowing the full risks attendant to that use.
 23 Such conduct was done with conscious disregard of Plaintiff’s welfare and rights.

26 CAUSE OF ACTION

27 I. COUNT I: STRICT PRODUCTS LIABILITY – FAILURE TO WARN

28 92. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as

1 if fully stated herein.

2 93. At all relevant times, Defendants engaged in the business of researching, testing,
3 developing, designing, manufacturing, labeling, marketing, selling, inspecting, distributing, and
4 promoting baby foods, which are defective and unreasonably dangerous to consumers, including
5 Plaintiff, because they do not contain adequate warnings or instructions concerning the dangerous
6 characteristics of baby foods in the form of the presence of Toxic Heavy Metals. These actions were
7 under the ultimate control and supervision of Defendants. At all relevant times, Defendants
8 registered, researched, manufactured, distributed, marketed, and sold baby foods and aimed at a
9 consumer market.
10

11 94. Defendants researched, tested, developed, designed, manufactured, labeled, marketed,
12 sold, inspected, distributed, and promoted, and otherwise released into the stream of commerce their
13 Contaminated Baby Foods, and in the course of same, directly advertised or marketed the products
14 to consumers and end users, including Plaintiff, and therefore had a duty to warn about the presence
15 of and risks associated with exposure to Toxic Heavy Metals from the consumption of Contaminated
16 Baby Foods.
17

18 95. At all relevant times, Defendants had a duty to properly test, develop, design,
19 manufacture, inspect, package, label, market, promote, sell, and distribute, maintain, supply, provide
20 proper warnings, and take such steps as necessary to ensure their Contaminated Baby Foods did not
21 cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a
22 continuing duty to warn Plaintiff of dangers associated with exposure to Toxic Heavy Metals from
23 consumption of the Contaminated Baby Foods. Defendants, as a manufacturer, seller, or distributor
24 of food, are held to the knowledge of an expert in the field.
25

26 96. At the time of manufacture, Defendants could have provided the warnings or
27
28

1 instructions regarding the full and complete risks of exposure to Toxic Heavy Metals in the
2 Contaminated Baby Foods because they knew or should have known of the unreasonable risks of
3 harm associated with the use of and/or exposure to such toxins.

4
5 97. At all relevant times, Defendants failed and deliberately refused to investigate, study,
6 test, or promote the safety or to minimize the dangers to users and consumers of their product and to
7 those who would foreseeably use or be harmed by exposure to the Toxic Heavy Metals in
8 Defendants' Baby Foods.

9
10 98. Even though Defendants knew or should have known that the presence of Toxic
11 Heavy Metals in Contaminated Baby Foods posed a risk of harm, they failed to exercise reasonable
12 care to warn of the dangerous risks associated with use and exposure to the toxins in the products.
13 The neurotoxic characteristic of Toxic Heavy Metals contained in Defendants' Contaminated Baby
14 Foods, as described above, were known to Defendants, or scientifically knowable to Defendants
15 through appropriate research and testing by known methods, at the time they distributed, supplied, or
16 sold the products, and were not known to end users and consumers, such as Plaintiff. The product
17 warnings for Contaminated Baby Foods in effect during the time period Plaintiff consumed those
18 foods were inadequate, both substantively and graphically, to alert consumers to the presence of and
19 health risks associated with exposure to the Toxic Heavy Metals from Contaminated Baby Food
20 consumption.
21

22
23 99. At all relevant times, Defendants' Contaminated Baby Foods reached the intended
24 consumers, handlers, and users or other persons coming into contact with these products, including
25 Plaintiff, without substantial change in their condition as manufactured, sold, distributed, labeled,
26 and marketed by Defendants.

27
28 100. Plaintiff was exposed to the Toxic Heavy Metals in Defendants' Contaminated Baby

1 Foods without knowledge of the potential for such exposure to Toxic Heavy Metals from
2 consumption of the products and the dangerous characteristics of the toxins.

3 101. At all relevant times, Plaintiff was exposed to the Toxic Heavy Metals in the
4 Defendants' Contaminated Baby Foods while consuming the foods for their intended or reasonably
5 foreseeable purposes, without knowledge of their dangerous characteristics.

6
7 102. Plaintiff could not have reasonably discovered the defects and risks associated with
8 exposure to the Toxic Heavy Metals in the Contaminated Baby Foods prior to or at the time of
9 Plaintiff consuming those foods. Plaintiff relied upon the skill, superior knowledge, and judgment of
10 Defendants to know about and disclose serious health risks associated with exposure to the toxins in
11 Defendants' products.

12
13 103. The information that Defendants did provide or communicate failed to contain
14 relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiff to
15 avoid consuming the products and, in turn, exposure to the Toxic Heavy Metals. Instead,
16 Defendants disseminated information that was inaccurate, false, and misleading, and which failed to
17 communicate accurately or adequately the comparative severity, duration, and extent of the risk of
18 injuries with use of and/or exposure to the Toxic Heavy Metals in the Contaminated Baby Foods;
19 continued to aggressively promote the safety of their products, even after they knew or should have
20 known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise
21 suppressed, through aggressive marketing and promotion, any information or research about the
22 risks and dangers of exposure to Toxic Heavy Metals from consumption of Contaminated Baby
23 Foods.

24 104. This alleged failure to warn is not limited to the information contained on
25 Contaminated Baby Foods labeling. The Defendants were able, in accordance with federal law, to
26
27
28

1 comply with relevant Florida state law, including §768.81 Fla. Stat. (2024), disclosing the known
2 risks associated with exposure to Heavy Metals in Contaminated Baby Foods through other non-
3 labeling mediums, i.e., promotion, advertisements, public service announcements, and/or public
4 information sources. But the Defendants did not disclose these known risks through any medium.
5 The ability to provide such warnings is not prohibited by any federal law.
6

7 105. Furthermore, Defendants possess a First Amendment Right to make truthful
8 statements about the products they sell, and no law could lawfully restrict that constitutional right.
9 This included making statements about the presence of and risks associated with Toxic Heavy
10 Metals in Contaminated Baby Foods.
11

12 106. Had Defendants provided adequate warnings and instructions and properly disclosed
13 and disseminated the risks associated with exposure to the toxins in their Contaminated Baby Foods,
14 Plaintiff could have avoided the risk of developing injuries and could have obtained or used
15 alternative products. However, as a result of Defendants' concealment of the dangers posed by the
16 Toxic Heavy Metals in their Contaminated Baby Foods, Plaintiff could not have averted their
17 exposures.
18

19 107. Defendants' conduct, as described above, was reckless. Defendants risked the lives
20 of babies and children, including Plaintiff, with knowledge of the safety problems associated with
21 Contaminated Baby Foods, and suppressed this knowledge from the general public. Defendants
22 made conscious decisions not to warn or inform the unsuspecting public.
23

24 108. The Defendants' lack of adequate warnings and instructions accompanying their
25 Contaminated Baby Foods caused Plaintiff's injuries.
26

27 109. As a direct and proximate result of the Defendants' failure to provide an adequate
28 warning of the risks of exposure to the Toxic Heavy Metals in their Contaminated Baby Foods,

1 Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment,
2 loss of enjoyment of life, economic loss and damages including, but not limited to past and future
3 medical expenses, lost income, and other damages.

4
5 110. **WHEREFORE**, Plaintiff respectfully requests this Court enter judgment in
6 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all
7 such other and further relief as this Court deems just and proper.

8 **II. COUNT II: STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT**

9
10 111. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as
11 if fully stated herein.

12 112. At all times herein mentioned, Defendants designed, manufactured, tested, marketed,
13 sold, handled, and distributed the Contaminated Baby Foods consumed by Plaintiff.

14 113. At all relevant times, the Contaminated Baby Foods consumed by Plaintiff were
15 expected to and did reach Plaintiff without a substantial change in their condition as manufactured,
16 handled, distributed, and sold by Defendants.

17
18 114. At all relevant times, the Contaminated Baby Foods consumed by Plaintiff were used
19 in a manner that was foreseeable and intended by Defendants.

20 115. The Contaminated Baby Foods consumed by Plaintiff were not reasonably safe for
21 their intended use and were defective with respect to their manufacture, as described herein, in that
22 Defendants deviated materially from their design and manufacturing specifications and/or such
23 design and manufacture posed an unreasonable risk of harm to Plaintiff. ¹Baby food should not,
24 by design, contain any detectable levels of Toxic Heavy Metals in them. Thus, Defendants'
25
26

27
28 ¹ If, through discovery and further litigation, it is discovered that Defendants' baby food products contained detectable levels of Toxic Heavy Metals by design, then Plaintiff will pursue a design defect claim (Count III) in the alternative.

1 Contaminated Baby Foods contain manufacturing defects.

2 116. The Defendants' Contaminated Baby Foods contained Toxic Heavy Metals because,
3 while in the control and possession of Defendants, they manufactured ingredients and used
4 manufacturing processes that result in the finished product being contaminated with Toxic Heavy
5 Metals. Had Defendants properly manufactured (directly or through co-manufacturers) the baby
6 foods, they would not have contained detectable levels of Toxic Heavy Metals in them and, thus,
7 would not have contained a manufacturing defect.
8

9 117. Nothing under federal law limited or restricted Defendants from taking action to
10 reduce or eliminate the Toxic Heavy Metals from being present in their baby foods.
11

12 118. This manufacturing defect caused Plaintiff to be exposed to Toxic Heavy Metals
13 through ingestion of the Contaminated Baby Foods which, in turn, caused neurodevelopmental harm
14 that manifested as ASD.
15

16 119. The exposure to the Toxic Heavy Metals in the Contaminated Baby Foods creates
17 risks to the health and safety of babies that are far more significant than the risks posed by non-
18 Contaminated Baby Food products, and which far outweigh the utility of the Contaminated Baby
19 Foods products because of Defendants' manufacturing defects.
20

21 120. Defendants have intentionally and recklessly manufactured the Contaminated Baby
22 Foods with wanton and willful disregard for the rights and health of Plaintiff, and with malice,
23 placing their economic interests above the health and safety of Plaintiff.

24 121. As a direct and proximate result of the Defendants' defective manufacture of the
25 Contaminated Baby Foods, Plaintiff has been injured, sustained severe and permanent pain,
26 suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including,
27 but not limited to medical expenses, lost income, and other damages.
28

1 122. **WHEREFORE**, Plaintiff respectfully requests this Court enter judgment in
2 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all
3 such other and further relief as this Court deems just and proper.

4
5 **III. COUNT III: STRICT PRODUCTS LIABILITY – DESIGN DEFECT**

6 123. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as
7 if fully stated herein.

8 124. At all times herein mentioned, Defendants designed, manufactured, tested, marketed,
9 sold, handled, and distributed the Contaminated Baby Foods consumed by Plaintiff. These actions
10 were under the ultimate control and supervision of Defendants.

11
12 125. At all relevant times, Defendants' Baby Food products were designed and labeled in
13 an unsafe, defective, and inherently dangerous manner that was dangerous for use or consumption by
14 infants and babies, including Plaintiff.

15 126. Defendants' Contaminated Baby Food products as researched, tested, developed,
16 designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants
17 were defective in design and formulation in that, when they were placed into the stream of
18 commerce, they were unreasonably dangerous and dangerous to an extent beyond that which an
19 ordinary consumer would contemplate.
20

21
22 127. Defendants' Contaminated Baby Food products, as researched, tested, developed,
23 designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants
24 were defective in design and formulation in that, when they left the hands of Defendants, the
25 foreseeable risks exceeded the alleged benefits associated with their design and formulation.

26 128. At all relevant times, the Contaminated Baby Food products consumed by Plaintiff
27 were expected to and did reach Plaintiff without a substantial change in its condition as designed,
28

1 manufactured, handled, distributed, and sold by Defendants.

2 129. At all relevant times, Defendants knew or had reason to know that their Contaminated
3 Baby Food products were defective and were inherently dangerous and unsafe when used in the
4 manner instructed and provided by Defendants.
5

6 130. Therefore, at all relevant times, Defendants' Baby Food products, as researched,
7 tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold
8 and marketed by Defendants were defective in design and formulation, in one or more of the
9 following ways:
10

- 11 A. When placed in the stream of commerce, Defendants' Contaminated Baby Food products
12 were unreasonably dangerous in that they contained Toxic Heavy Metals that posed a risk
13 of causing interference with neurodevelopment in babies that manifests as the
14 neurodevelopmental disorders ASD, ADHD and related sequelae when used in a
15 reasonably anticipated manner;
16
- 17 B. When placed in the stream of commerce, Defendants' designed Contaminated Baby Food
18 products to contain unreasonably dangerous design defects and were not reasonably safe
19 when used in a reasonably anticipated or intended manner;
20
- 21 C. Defendants, by design, did not sufficiently test, investigate, or study their Contaminated
22 Baby Food products;
23
- 24 D. Exposure to the Toxic Heavy Metals in Defendants' Contaminated Baby Food products
25 present a risk of harmful effects that outweigh any potential utility stemming from their
26 use;
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- 28 E. Defendants, by design, did not conduct adequate post-marketing surveillance of their
Contaminated Baby Food products which would have alerted the public to risks; and

1 F. Defendants could have employed safer alternative designs and formulations for
2 Contaminated Baby Foods, such as ensuring the baby food did not have any detectable
3 level of Toxic Heavy Metals.

4
5 131. Plaintiff consumed Defendants' Contaminated Baby Food products in an intended or
6 reasonably foreseeable manner without knowledge of their dangerous characteristics.

7 132. Defendants' Contaminated Baby Food products were and are more dangerous than
8 alternative products, and Defendants could have designed their Contaminated Baby Food products to
9 avoid harm to children. Indeed, at the time Defendants designed the Contaminated Baby Food
10 products, the state of the industry's scientific knowledge was such that a less risky design or
11 formulation was attainable.

12
13 133. At the time the Contaminated Baby Food products left Defendants' control, there was
14 a practical, technically feasible, and safer alternative design that would have prevented the harm
15 without substantially impairing the reasonably anticipated or intended function of Defendants'
16 Contaminated Baby Foods.

17
18 134. Defendants intentionally and recklessly defectively designed the Contaminated Baby
19 Foods with wanton and willful disregard for the rights and health of Plaintiff, and with malice,
20 placing their economic interests above the health and safety of Plaintiff.

21
22 135. The design defects in Defendants' Contaminated Baby Foods were substantial factors
23 in causing Plaintiff' injuries.

24 136. As a direct and proximate result of the Defendants' defective design of the
25 Contaminated Baby Foods, Plaintiff has been injured, sustained severe and permanent pain,
26 suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including,
27 but not limited to medical expenses, lost income, and other damages.
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1 137. **WHEREFORE**, Plaintiff respectfully requests this Court enter judgment in
2 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all
3 such other and further relief as this Court deems just and proper.

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5 **IV. COUNT IV: NEGLIGENCE – FAILURE TO WARN**

6 138. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as
7 if fully stated herein.

8 139. At all relevant times, Defendants engaged in the business of testing, developing,
9 designing, manufacturing, marketing, selling, distributing, and promoting baby foods. Defendants
10 knew, or, by the exercise of reasonable care, should have known that their Contaminated Baby
11 Foods are not accompanied with adequate warnings concerning the dangerous characteristics of
12 exposure to Toxic Heavy Metals from consumption. These actions were under the ultimate control
13 and supervision of Defendants.

14
15 140. Defendants researched, developed, designed, tested, manufactured, inspected, labeled,
16 distributed, marketed, promoted, sold, and otherwise released into the stream of commerce their
17 Contaminated Baby Foods, and in the course of same, directly advertised or marketed the products
18 to consumers and end users, including Plaintiff, and therefore had a duty to warn of the risks
19 associated with the presence of and exposure to Toxic Heavy Metals from consumption of
20 Contaminated Baby Foods.

21
22 141. At all relevant times, Defendants had a duty to properly test, develop, design,
23 manufacture, inspect, package, label, market, promote, sell, distribute, maintain, supply, provide
24 proper warnings, and take such steps as necessary to ensure their Contaminated Baby Foods did not
25 cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a
26 continuing duty to warn Plaintiff of dangers associated with the presence of and exposure to Toxic
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1 Heavy Metals from consumption of Contaminated Baby Foods. Defendants, as a manufacturer,
2 seller, or distributor of food products, are held to the knowledge of an expert in the field.

3 142. At the time of manufacture, Defendants could have provided warnings regarding the
4 presence of and risks of exposure to Toxic Heavy Metals from consumption of Contaminated Baby
5 Foods because they knew or should have known exposure to Toxic Heavy Metals from consumption
6 of Contaminated Baby Foods was dangerous, harmful and injurious when the Contaminated Baby
7 Foods were consumed by Plaintiff in a reasonably foreseeable manner.

8 143. At all relevant times, Defendants failed and deliberately refused to investigate, study,
9 test, or promote the safety or to minimize the dangers to users and consumers of their products and
10 to those who would foreseeably use or be harmed by Defendants' Contaminated Baby Foods.

11 144. Defendants knew or should have known that exposure to Toxic Heavy Metals from
12 consumption of Contaminated Baby Foods posed a risk of harm, but failed to exercise reasonable
13 care to warn of the dangerous risks associated with use and exposure to the toxins in the products.
14 The dangerous propensities of exposure to Toxic Heavy Metals from consumption of the
15 Contaminated Baby Foods, as described above, were known to Defendants, or scientifically
16 knowable to Defendants through appropriate research and testing by known methods, at the time
17 they distributed, supplied, or sold the products, and were not known to end users and consumers,
18 such as the Plaintiff.

19 145. At all relevant times, Plaintiff was exposed to Toxic Heavy Metals through
20 consumption of the Contaminated Baby Foods while using the products for their intended or
21 reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

22 146. Defendants knew or should have known that the non-extant warnings disseminated
23 with their Contaminated Baby Foods were inadequate, failed to communicate adequate information
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1 on the presence of and dangers of exposure to toxins contained therein, and failed to communicate
2 warnings and instructions that were appropriate and adequate to render the products safe for their
3 ordinary, intended and reasonably foreseeable uses.

4
5 147. The information that Defendants did provide or communicate failed to contain
6 relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiff to
7 avoid using the product and, in turn, prevented exposure to the Toxic Heavy Metals contained
8 therein. Instead, Defendants disseminated information that was inaccurate, false, and misleading,
9 and which failed to communicate accurately or adequately the comparative severity, duration, and
10 extent of the risk of injuries with use of and/or exposure to the Toxic Heavy Metals in the
11 Contaminated Baby Foods; continued to aggressively promote the efficacy of their products, even
12 after they knew or should have known of the unreasonable risks from use or exposure to the toxins
13 contained therein; and concealed, downplayed, or otherwise suppressed, through aggressive
14 marketing and promotion, any information or research about the risks and dangers of exposure to
15 Toxic Heavy Metals from consumption of the Contaminated Baby Foods.

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18 148. A reasonable company under the same or similar circumstance would have warned
19 and instructed of the dangers of exposure to Toxic Heavy Metals from consumption of Contaminated
20 Baby Foods.

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22 149. This alleged failure to warn is not limited to the information contained on the labeling
23 of Defendants' Contaminated Baby Foods. Defendants were able, in accord with federal law, to
24 comply with relevant state law by disclosing the known risks associated with exposure to Toxic
25 Heavy Metals from consumption of Contaminated Baby Foods through other non-labeling mediums,
26 i.e., promotion, advertisements, public service announcements, and/or public information sources.
27 But the Defendants did not disclose these known risks through any medium.
28

1 150. Furthermore, Defendants possess a First Amendment Right to make truthful
2 statements about the products they sell, and no law could lawfully restrict that constitutional right.

3 151. Had Defendants provided adequate warnings and instructions and properly disclosed
4 and disseminated the risks associated with the presence of and exposure to Toxic Heavy Metals in
5 the Contaminated Baby Foods, Plaintiff could have avoided the risk of developing injuries and could
6 have obtained or used alternative products. However, as a result of Defendants' concealment of the
7 dangers posed by their Contaminated Baby Foods, Plaintiff could not have averted their injuries.

8 152. Defendants' conduct, as described above, was reckless. Defendants risked the lives of
9 consumers and users of their products, including Plaintiff, with knowledge of the safety problems
10 associated with Contaminated Baby Foods, and suppressed this knowledge from the general public.
11 Defendants made conscious decisions not to warn or inform the unsuspecting public.

12 153. The Defendants' lack of adequate warnings and instructions accompanying their
13 Contaminated Baby Foods were a substantial factor in causing Plaintiff's injuries.

14 154. As a direct and proximate result of the Defendants' failure to provide an adequate
15 warning of the risks of exposure to Toxic Heavy Metals from consumption of Contaminated Baby
16 Foods, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability,
17 impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past
18 and future medical expenses, lost income, and other damages.

19 155. **WHEREFORE**, Plaintiff respectfully requests this Court enter judgment in
20 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all
21 such other and further relief as this Court deems just and proper.

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23 **V. COUNT V: NEGLIGENCE - MANUFACTURING**

24 156. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as
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1 if fully stated herein.

2 157. At all relevant times, the Defendants manufactured, tested, marketed, sold, and
3 distributed the Contaminated Baby Foods that Plaintiff consumed.

4 158. The Defendants had a duty to exercise reasonable care, in the manufacturing, testing,
5 marketing, sale, and distribution of baby foods.

6 159. The Defendants knew or, by the exercise of reasonable care, should have known, that
7 exposure to Toxic Heavy Metals from consumption of Contaminated Baby Foods rendered the foods
8 carelessly manufactured, dangerous, harmful and injurious when used by Plaintiff in a reasonably
9 foreseeable manner.

10 160. The Defendants knew or, by the exercise of reasonable care, should have known,
11 ordinary consumers such as Plaintiff would not have realized the potential risks and dangers of
12 exposure to Toxic Heavy Metals from consumption of Contaminated Baby Foods.

13 161. Without limitation, examples of the manner in which Defendants breached their duty
14 to exercise reasonable care in manufacturing Contaminated Baby Foods, included:

- 15 A. Failure to adequately inspect/test the Contaminated Baby Foods, and their ingredients,
16 during and after the manufacturing process;
17 B. Failure to implement procedures that would reduce or eliminate Toxic Heavy Metals in
18 baby foods;
19 C. Failure to investigate suppliers and ingredient sources to reduce and eliminate the risk of
20 ingredients containing Toxic Heavy Metals; and
21 D. Failure to avoid using ingredients free from, or which contain far less, Toxic Heavy
22 Metals to manufacture baby food.

23 162. A reasonable manufacturer under the same or similar circumstances would have
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1 implemented appropriate manufacturing procedures to better ensure the quality and safety of their
2 product.

3 163. Plaintiff was harmed directly and proximately by the Defendants' failure to use
4 reasonable care in the manufacture of their Contaminated Baby Foods. Such harm includes
5 exposure to Toxic Heavy Metals, which can cause or contribute to interference with early
6 neurodevelopment which manifests as ASD, ADHD, and related *sequelae*.

7 164. Defendants' improper manufacturing of Baby Foods was willful, wanton, malicious,
8 and conducted with reckless disregard for the health and safety of users of the Contaminated Baby
9 Foods, including Plaintiff.

10 165. The defects in Defendants' Contaminated Baby Foods were substantial factors in
11 causing Plaintiff's injuries.

12 166. As a direct and proximate result of the Defendants' improper manufacturing of
13 Contaminated Baby Foods, Plaintiff has been injured, sustained severe and permanent pain,
14 suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including,
15 but not limited to past and future medical expenses, lost income, and other damages.

16 167. **WHEREFORE**, Plaintiff respectfully requests this Court enter judgment in
17 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all
18 such other and further relief as this Court deems just and proper.

19 **VI. COUNT VI: NEGLIGENCE – PRODUCT DESIGN**

20 168. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as
21 if fully stated herein.

22 169. Defendants knew or, by the exercise of reasonable care, should have known, ordinary
23 consumers such as Plaintiff would not have realized the potential risks and dangers of Contaminated
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1 Baby Foods.

2 170. The Defendants owed a duty to all reasonably foreseeable users to design a safe
3 product.

4 171. The Defendants breached their duty by failing to use reasonable care in the design of
5 Contaminated Baby Foods because the products exposed babies to Toxic Heavy Metals.

6 172. The Defendants breached their duty by failing to use reasonable care in the design of
7 Contaminated Baby Foods by negligently designing the foods with ingredients and/or components
8 contaminated with Toxic Heavy Metals.

9 173. The Defendants breached their duty by failing to use reasonable care in the design of
10 Contaminated Baby Foods by negligently designing and formulation, in one or more of the
11 following ways:

12 A. When placed in the stream of commerce, Defendants' Contaminated Baby Foods were
13 defective in design and formulation, and, consequently, dangerous to an extent beyond
14 that which an ordinary consumer would contemplate;

15 B. When placed in the stream of commerce, Defendants' Contaminated Baby Foods were
16 unreasonably dangerous in that they were hazardous and posed a risk of
17 neurodevelopmental disorders and other serious illnesses when used in a reasonably
18 anticipated manner;

19 C. When placed in the stream of commerce, Defendants' Contaminated Baby Foods
20 contained unreasonably dangerous design defects and were not reasonably safe when
21 used in a reasonably anticipated or intended manner;

1 D. Defendants did not sufficiently test, investigate, or study their Contaminated Baby Foods
2 and, specifically, the content of Toxic Heavy Metals in the ingredients used to
3 manufacture the foods and/or the finished products;

4 E. Defendants did not sufficiently test, investigate, or study their Contaminated Baby Foods
5 and, specifically, the ability for those foods to expose babies to Toxic Heavy Metals; and
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7 F. Exposure to the Toxic Heavy Metals in Contaminated Baby Foods presents a risk of
8 harmful effects that outweigh any potential utility stemming from the use of the products;
9

10 174. Defendants knew or should have known at the time of marketing Contaminated Baby
11 Foods that exposure to Toxic Heavy Metals contained in the Baby Foods could result in interference
12 with early neurodevelopment that that manifests as ASD, ADHD and other severe illnesses and
13 injuries.

14 175. Defendants, by design, did not conduct adequate post-marketing surveillance of their
15 Contaminated Baby Foods.
16

17 176. Defendants could have employed safer alternative designs and formulations. For
18 example, the Defendants could have avoided use of certain ingredients contaminated with Toxic
19 Heavy Metals, avoided using pre-mix vitamins contaminated with Toxic Heavy Metals, and/or
20 sampled their ingredients from other sources.
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22 177. The Defendants breached their duty by failing to use reasonable care by failing to use
23 cost effective, reasonably feasible alternative designs. There was a practical, technically feasible,
24 and safer alternative design that would have prevented the harm without substantially impairing the
25 reasonably anticipated or intended function of Defendants' Contaminated Baby Foods.

26 178. A reasonable company under the same or similar circumstances would have designed
27 a safer product.
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1 179. Plaintiff was harmed directly and proximately by the Defendants' failure to use
2 reasonable care in the design of their Contaminated Baby Foods. Such harm includes exposure to
3 Toxic Heavy Metals, which can cause or contribute to interference with neurodevelopment that
4 manifests as ASD, ADHD, and related *sequelae*.
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6 180. Defendants' defective design of Contaminated Baby Foods was willful, wanton,
7 malicious, and conducted with reckless disregard for the health and safety of consumers of the Baby
8 Foods, including Plaintiff.
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10 181. The defects in Defendants' Contaminated Baby Foods were substantial factors in
11 causing Plaintiff's injuries.

12 182. As a direct and proximate result of the Defendants' negligent design of the
13 Contaminated Baby Foods, Plaintiff have been injured, sustained severe and permanent pain,
14 suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including,
15 but not limited to past and future medical expenses, lost income, and other damages.
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17 183. **WHEREFORE**, Plaintiff respectfully requests this Court enter judgment in
18 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all
19 such other and further relief as this Court deems just and proper.
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21 **VII. COUNT VII: GENERAL NEGLIGENCE**

22 184. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as
23 if fully stated herein.

24 185. Plaintiff pleads claims for negligence under all theories that may be actionable under
25 §768.81 Fla. State. (2024).
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27 186. Defendants owed Plaintiff a duty to act with reasonable care.
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- 1 A. Defendants owed a duty because they distributed and promoted their products as safe for
2 children to consume.
- 3 B. Defendants owed a duty because their conduct created a risk of harm to Plaintiff and caused
4 Plaintiff actual harm.
- 5 C. Defendants owed a duty because the risk of harm to Plaintiff was embedded in, and an
6 inherent component of, their negligent business practices.
- 7 D. Defendants owed a duty because they designed, manufactured, controlled, distributed, and
8 sold their products to Plaintiff.

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10 187. Defendants breached their duty to Plaintiff.

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12 188. Defendants' negligence includes, but is not limited to, their marketing, designing
13 manufacturing, producing, supplying, inspecting, testing, selling and/or distributing Contaminated
14 Baby Foods in one or more of the following respects:

- 15 A. Failure to implement procedures that would reduce or eliminate Toxic Heavy Metals in baby
16 foods;
- 17 B. Failure to investigate suppliers and ingredient sources to reduce and eliminate the risk of
18 ingredients containing Toxic Heavy Metals; and
- 19 C. Failure to avoid using ingredients free from, or which contain far less, Toxic Heavy Metals to
20 manufacture baby food.
- 21 D. When placed in the stream of commerce, Defendants' Contaminated Baby Foods were
22 defective in design and formulation, and, consequently, dangerous to an extent beyond that
23 which an ordinary consumer would contemplate;
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1 E. When placed in the stream of commerce, Defendants' Contaminated Baby Foods were
2 unreasonably dangerous in that they were hazardous and posed a risk of neurodevelopmental
3 disorders and other serious illnesses when used in a reasonably anticipated manner;

4 F. When placed in the stream of commerce, Defendants' Contaminated Baby Foods contained
5 unreasonably dangerous design defects and were not reasonably safe when used in a
6 reasonably anticipated or intended manner;

7 G. Defendants, by design, did not conduct adequate post-marketing surveillance of their
8 Contaminated Baby Food products which would have alerted the public to risks; and

9 H. Defendants did not sufficiently test, investigate, or study their Contaminated Baby Foods
10 and, specifically, the ability for those foods to expose babies to Toxic Heavy Metals;

11 I. Defendants could have employed safer alternative designs and formulations for
12 Contaminated Baby Foods, such as ensuring the baby food did not have any detectable level
13 of Toxic Heavy Metal.

14 J. Defendants did not sufficiently test, investigate, or study their Contaminated Baby Foods
15 and, specifically, the content of Toxic Heavy Metals in the ingredients used to manufacture
16 the foods and/or the finished products; and

17 K. Exposure to the Toxic Heavy Metals in Contaminated Baby Foods presents a risk of harmful
18 effects that outweigh any potential utility stemming from the use of the products;

19 189. Defendants knew or should have known that their products contained detectable
20 levels of heavy metals that created an unreasonable risk of harm to children who consumed their
21 products.

22 190. At all relevant times, the Defendants knew or should have known that the Products
23 were unreasonably dangerous and defective when put to their reasonably anticipated use.
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1 191. As a proximate result of Defendants' negligence, Plaintiff has been injured, sustained
2 severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic
3 loss, and damages including, but not limited to past and future medical expenses, lost income, and
4 other damages.
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6 192. **WHEREFORE**, Plaintiff respectfully requests this Court enter judgment in
7 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all
8 such other and further relief as this Court deems just and proper.
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11 **JURY TRIAL DEMAND**

12 193. Plaintiff demands a trial by jury on all the triable issues within this pleading.
13

14 **PRAYER FOR RELIEF**

15 194. **WHEREFORE**, Plaintiff requests that the Court enter judgment in Plaintiff's favor
16 and against the Defendants for:

- 17 **a.** actual or compensatory damages in such amount to be determined at trial and as provided
18 by applicable law;
19 **b.** exemplary and punitive damages sufficient to punish and deter the Defendants and others
20 from future wrongful practices;
21 **c.** pre-judgment and post-judgment interest;
22 **d.** costs including reasonable attorneys' fees, court costs, and other litigation expenses; and
23 **e.** any other relief the Court may deem just and proper.
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DATED this 14th Day of February, 2025.

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